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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,981	01/25/2001	Aladar A. Szalay	13070-1	5416

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SHELDON & MAK  
Attn: David A. Farah, M.D.  
225 South Lake Avenue, Suite 900  
Pasadena, CA 90101

EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/769,981

Applicant(s)

SZALAY ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-12 and 33-62 is/are pending in the application.
- 4a) Of the above claim(s) 33-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Amendment Entry***

1. The amendment filed September 19, 2005 has been entered. Claim 1 has been amended. Claims 6 and 13-32 have been canceled. Claims 33-62 have been newly added.

### ***Election/Restrictions***

2. Newly submitted claims 33-62 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: Applicants urge that new claims contain limitations present in the originally elected claims. This is not found persuasive because the methods described in claims 33-62 are patentably distinct. The methods are distinct as claimed because claims have different method steps, with different functions and those effects result in different final outcomes. For instance, claims 33-42 are drawn to a method for evaluating whether a material will allow bacteria to pass through, around or into the material using a distinctly different modified bacteria, i.e., a bacteria that comprises two separately detectable signals. Moreover, claims 43-52 are drawn to an evaluation method wherein the method places the modified bacteria in the center of a hollowed out, extracted natural tooth where the root end of the tooth is sealed with the material, thus this method has a different function. The method of claim 1 is not drawn to an evaluation method wherein the method places the modified bacteria in the center of a hollowed out, extracted natural tooth where the root end of the tooth is sealed with the material, thus this method has a different function. Furthermore, the methods of claims 33-62 do not produce the same

results. The groups produce different effects and different functions when compared to the other group. Therefore, the inventions are unrelated. The requirement is still deemed proper and is therefore made FINAL.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33-62 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Therefore, claims 1-5 and 7-12 are under consideration in this office action.

#### ***Withdrawal of Rejections***

4. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 1-2, 4, 7 and 11 under 35 U.S.C. 102(b) as being anticipated by Loessner et al; and

b) The rejection of claims 1-8 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/356,245.

***Response to Arguments***

5. Applicant's arguments filed September 19, 2005 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The rejection of claims 1-5, 7-8, 11-12 under 35 U.S.C. 103(a) as being unpatentable over Miller et al., (US Patent 5,736,351) in view of Billiard et al., is maintained for reasons already of record.

The rejection was on the grounds that Miller et al., (US Patent 5,736,351) in view of Billiard et al., taught a method for evaluating whether an implantable material will allow modified living bacteria to pass through the implantable material or around the implantable material or into the implantable material comprising: a) providing living bacteria which are modified to produce a first detectable signal; b) placing the modified bacteria on a first side of the implantable material being evaluated; and c) detecting whether the first signal in the visible spectrum is present on a second side of the implantable material or within the implantable; where the absence of the first signal on the second side of the implantable material or within the implantable material indicates that the modified living bacteria have not passed through or around the implantable

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material and where presence of the first signal on the second side of the implantable material or within the implantable material or within the implantable material indicates that the modified living bacteria have passed through or around the implantable material; where the implantable material is non-living; and where the modified living bacteria are modified to incorporate a functional green fluorescent protein.

Applicants point to the use of a disposable test device and determination of the amount of ATP present measuring the light emitted through translucent sides of the disposable device and the provision of disposable test device to detect the microbes as evidence that Miller et al., teach away from the instant invention. However, there is no limitation within the claims on how the detection of the signal occurs. Miller et al., teach a photometer that accommodates the test device in a manner that allows for its precise positioning with respect to the location being detected. Thus, Miller et al., teach detecting whether the first signal in the visible spectrum is present on a second side or any location of the implantable material. Moreover, the use of a test device does not teach away from the instant claims since Miller et al., teach the ability to swab any location on the material to thereby detect a signal. The claims encompass the detection of the bacteria which passed through the implantable material or around the implantable material or into the implantable material, therefore detection in any location which is not the first location yet may still be on a surface is embraced. Thus, the teaching of Miller et al., meet the instantly claimed limitation. Applicants' statement about the surface as used in Miller et al., is not persuasive, since the only limitation of the first and second

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side is that they are different locations. Miller et al, broadly teaches the ability to detect the bacterium at any location, contrary to applicants statements.

Moreover, applicant asserts that Miller et al., are teaching away from the instant claims by using a bacterial lysate to produce a detectable signal. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking the Miller et al., reference individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Billard et al., teach the introduction of genes encoding luciferase wherein a host bacterium provides for a detectable signal. Thus, Billard et al., teach a living modified host bacterium which has incorporated functional luciferase protein, just as required by the claims.

Finally, the teaching of Miller et al., is not limited to the one embodiment exemplified by applicants. The MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See

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also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). Moreover, Miller et al., do not need to recite the exact same language as the instant claims to teach the instantly recited steps. Miller et al., clearly teach detection at any location. Therefore applicant's argument is not persuasive especially when considering that it would have been prima facie obvious at the time of applicants' invention to modify the methods of Miller et al., to detect bacterial contamination using bacteria that produces a detectable signal and incorporate a modified living bacterium that expresses GFP and/or luciferase to produce a detectable signal as taught by Billard et al., in the method of evaluating an implantable material wherein detection of the bacteria can occur in any location. One would have a reasonable expectation of success because no more than routine skill would have been required to exchange the modified bacteria of for the well-known modified living bacteria of Billard et al., which was also known in the art to be useable to detect bacterial contamination, contrary to applications assertion. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5



USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, no more than routine skill would have been required to make the modified bacteria that was already known in the art to be able to detect the bacteria. Moreover, no more than routine skill is required to use a well-known alternative and functionally equivalent luminescent reporter in a modified bacterium that is known in the art to be useful for the purpose of signal detection. And there would have been a reasonable expectation of success by one skilled in the art since GFP and luciferase expression techniques are well known in the art to be rapid, not require exogenous reagents and convenient when compared to other detection methods. Therefore the rejection is maintained for reasons already of record.

7. The rejection of claims 9-10 and 12 under 35 U.S.C. 103(a) as being unpatentable over Miller et al., (US Patent 5,736,351) and Contag et al., and further in view of Holen (US Patent 5,814,331) is maintained. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants' invention to modify the methods taught by Miller et al., and Contag et al., to detect bacterial contamination on teeth as taught by Holen.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

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*Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one would have a reasonable expectation of success because no more than routine skill would have been required to exchange the materials of Miller et al., and Contag et al., for a tooth, since the art teaches that bacterial contamination of teeth can cause periodontal diseases. Moreover, no more than routine skill would have been required to exchange the material being tested because it was already known in the art to be able to detect the bacteria on tooth surfaces. Thus, applicants' assertions are not persuasive and the rejection is maintained.

### ***Conclusion***

8. No claims allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines   
November 21, 2005

  
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